

## **REMARKS**

### ***Summary of the Interview***

Applicants and Applicants' representatives thank the Examiners for the courtesies extended in the interview of December 20, 2007. In the interview, the written description and obviousness rejections were discussed. The Examiners indicated that the written description rejection would be withdrawn on the submission of references showing that a substantial number of proliferation and cell cycle control proteins are known in the art. The Examiners also indicated that evidence of surprisingly improved results provided by the presently claimed methods for screening physiologically active substances as compared to the screening method disclosed by Bounaga et al. would be considered in demonstrating the non-obviousness of the instant claims.

### ***1. Claim Rejections under 35 USC Section 112 -- Written Description***

On pages 4-7 and 18-20 of the Office Action, the Examiner maintains the previously imposed written description rejection of claims 1-6 and imposes a similar written description rejection against new claims 21-22 and 25. Applicants respectfully traverse.

As discussed above in the Summary of the Interview Section, the Examiner indicated that the written description rejection would be withdrawn upon a showing that a substantial number of proliferation and cell cycle proteins are known in the art. To this end, Applicants first reaffirm their position that the scientific publications submitted in the May 29, 2007 Amendment establish that a substantial number of proliferation and cell cycle control proteins are known in the art for at least the reasons recited in the May 29, 2007 Amendment.

In addition, Applicants submit with this paper the following 8 publications:

Publication 1: *Molecular Biology of the Cell*, (1999): 10, 2703-2734.

Publication 2: *Breast Cancer Res.*, (2000): 2:116-124.

Publication 3: *Oncogene*, (1999): 18, 7432-7441.

Publication 4: *The Journal of Biological Chemistry*, (2000) 275(20), 15254-15264.

Publication 5: *Breast Cancer Research*, (2002): (4): 70-76.

Publication 6: *The EMBO Journal*, (1986): 5(6), 1351-1358.

Publication 7: *The Journal of Biological Chemistry*, (1992): 267(28): 20412-20415.

Publication 8: *Genome Res.*, (2001): 11:1899-1912

Applicants submit that these publications independently establish that proliferation and cell cycle control proteins are known in the art for at least the following reasons:

**1.A Proteins and Genes Involved in Cell Cycle and Cell Proliferation**

**Publication 1:** Figures 1 to 6 and Table 1 of this publication disclose a total of 116 proteins and genes involved in cell cycle and cell proliferation, of which the following genes are set forth in concrete examples:

- Cyclin family (Cyclin A, Cyclin E, Cyclin D, Cyclin E)
- Cyclin dependent kinase family (cdk1, cdk2, cdk4, cdk6)
- P53
- E2F family (E2F1, E2F2, E2F3, E2F4, E2F5, E2F6)
- P21
- GADD45
- PARP
- Kinase inhibitor protein family (p21, p27, p57)
- Cdk-activating kinase family (cdk7, Cyclin H, Mat1)
- Retinoblastoma protein family (pRb, p107, p130)
- ARF family (p14, p19)

**Publication 2:** Figure 1 of this publication discloses the following proteins and genes involved in cell cycle and cell proliferation:

- TGF- $\beta$
- INK4 family (p15, p16, p18 and p19)

**Publication 3:** Abstract and page 7433, left column of this publication disclose the following proteins or genes involved in cell cycle and cell proliferation:

- Tob/BTG1 family (Tob, Tob2, BTG1, PC3/TIS21/BTG2, ANA/BTG3)
- Caf1

**Publication 4:** The right column, second paragraph of page 15254 of this publication discloses the following proteins or genes involved in cell cycle and cell proliferation:

- Histone deacetylase family (HDAC1, HDAC2, HDAC3, HDAC4, HDAC5,
- HDAC6, HDAC7, HDAC8)

**Publication 5:** The right column, third paragraph of page 74 of this publication discloses the following proteins or genes involved in cell cycle and cell proliferation:

- P53 family (p53, p63, p73)

### **1.B Gene Cloning**

**Publication 3:** The left column, third paragraph of page 7440 of this publication discloses a case where Tob2 is expressed in a transformed yeast.

**Publication 4:** Abstract of this publication discloses a case where Histone deacetylase is expressed in transformed HEK293 cells.

**Publication 6:** This publication discloses a case where p21 is expressed in transformed *Escherichia coli* cells.

**Publication 7:** Abstract of this publication discloses a case where Cyclin D is expressed in transformed HeLa cells.

**Publication 8:** Tables 1 and 2 of this publication disclose cases where various kinds of genes are introduced into yeast. Especially, Table 1 of this publication discloses a case where PARP1, involved in cell cycle and cell proliferation, is expressed in a transformed yeast, and Table 2 discloses cases where PARP1, p13 kinase, and p38, each involved in cell cycle and cell proliferation, are expressed in transformed yeast.

## ***2. Claim Rejections under 35 USC Section 103***

On pages 7-17 of the Office Action, the Examiner imposes a series of obviousness rejections against the pending claims. Applicants respectfully traverse.

Applicants disagree with Examiner, and maintain that the presently pending claims are nonobvious over the prior art of record for the reasons set forth in the May 29, 2007 Amendment. In addition, Applicants have submitted together with this paper a request for six month suspension of examination in order to prepare and file comparative data showing that the presently claimed screening methods provide surprisingly improved results as compared to the screening method taught by Buonaga et al.

## ***3. Conclusion***

In view of the above-presented amendments and remarks, Applicants respectfully request immediate allowance of all pending claims, which define subject matter that meets all statutory patentability requirements.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact John Burr, Registration No 58,475, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

- ☒ Attached is a Petition for Extension of Time.
- ☒ Attached hereto is the fee transmittal listing the required fees.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: January 24, 2008

Respectfully submitted,

By 

Gerald M. Murphy, Jr.

Registration No.: 28,977

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant